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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,891	04/30/2002	Ronald R. Marquardt	3027.00020	6701

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EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,891	MARQUARDT ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/16/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites "removing a quantity of detectable label form the sample by binding detectable label to the reactant coated on the reaction vessel", (lines 9-10) is vague and confusing because it is unclear as to how a quantity of the label is removed from the sample by binding. Is the label cleaved from the reactant? This limitation is not clear.

5. Claim 10 recites teaches releasing a quantity of detectable label from the reactant by incubating the reaction vessel under condition such that the reactant and the detectable label contact the bioactive molecule and interact with the bioactive molecule, (lines 7-9) is confusing because it is unclear as to how the label is being released. Is the label being cleaved? This limitation is not clear.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,610,494. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claimed invention measures the activity or concentration of a bioactive molecule comprising coating a reaction vessel with a reactant, (first component) adding a sample to the reaction vessel that comprise of a detectable label

of known quantity and a bioactive molecule having a biological activity. The biological activity can be the reaction vessel which is incubated under conditions wherein the reactant and the sample interact; a quantity of detectable label is removed from the sample by binding detectable label to the reactant coated on the reaction vessel; transferring a soluble portion of the sample from the reaction vessel to a counting vessel; and measuring the quantity of detectable label in the counting vessel. Claims 6-7 and 15-16 further includes a third component, which can be an inhibitor or a competitor of the bioactive molecule. The biological activity can be hydrolysis and other enzymatic activity (specification, page 8).

Claim 1-6 of Patent No. 6,610,494 is encompassed by the above claimed invention because it teaches determining an amount of inhibitor of a hydrolase by measuring the inhibition activity of the hydrolase. The steps include adding a first component conjugated to an indicator that is bound to the surface of a vessel. A second component having a known hydrolase activity that reacts with the first component. An unknown amount of third component which an inhibitor of the second component is also added to the reaction mixture under condition such that the first and second components will hydrolyze the first component and remove the indicator (label) from the surface of the vessel and the third component being an inhibitor will interfere with the reaction between the first and second components of the assay (column 6, lines 40-67, column 7, lines 1-27, 55-67, column 8, lines 19-67). When the indicator is hydrolyzed, it will be released into the sample, removed and measured by an ELISA plate reader (column 8, lines 28-35).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Marquardt et al (WO 97/43438).

The claims are drawn to a method for measuring the activity or concentration of a bioactive molecule comprising coating a reaction vessel with a reactant, adding a sample to the reaction vessel comprising a known quantity of a detectable label and the bioactive molecule, incubating the reactinon vessel under conditions wherein the reactant and the sample interact; removing a quantity of detectable label from the sample by binding detectable label to the reactant coated on the reaction vessel; transferring a soluble portion of the sample form the reaction vessel to a counting vessel; and measuring the quantity of detectable label in the counting vessel.

The reference of Marquardt et al teaches detecting the amount of biological activity of a biologically active molecule. A sample containing a known quantity of a second component having a biological activity is bound to the surface of a reaction vessel. Also, a sample containing an unknown quantity of the second component and a known quantity of an indicator bound to a first component is added to a reaction. The reaction is run under conditions such that the first and second components will bind due

to biologic activity. The sample is removed after the reaction is complete (page 5). For example, one embodiment teaches that coated substrates containing one cleavage site, could be cleaved by an enzyme component conjugated to an indicator that binds to the substrate on the reaction vessel and cleave the indicator releasing it into the media which is then removed (soluble portion of the sample) (page 17, lines 24-35) and measured. An ELISA reader (counting vessel) can be used to measure absorbency and calculate results of the assay (page 25, lines 17-22). This assay can be competitive or non-competitive and non-competitive, where the components of the assay can involve an enzyme and an inhibitor of the enzyme acting on a substrate (page 13, lines 1-11). The detectable label can be enzyme or fluorescent (page 14, lines 1-7). The bioactive molecule can be enzymes, lectins, receptors and cell adhesion molecules (page 12, lines 28-34). One embodiment teaches that the reactant can bound to the vessel can already be conjugated to a label before the addition of the sample, as recited in claim 10 (page 16, lines 3-36).

Conclusion

10. No claims are allowed.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A: Bolguslaski et al teaches heterogenous specific binding assays employing enzyme substrates (USP#4492751).

B: Burbaum et al teaches homogeneous high throughput assays which screens compounds for enzyme inhibition or other target binding (USP#5876946).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

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February 14, 2005